REMARKS/ARGUMENTS

Claims 5-7 and 12-23 are active. Claims 1-4, 8 and 9 have been withdrawn from consideration. Independent claim 5 has been revised to refer to the process steps of claim 1. It is now a product-by-process claim. Claims 3, 13 and 14 include minor corrections. Claim 25 has been further limited. Accordingly, the Applicants do not believe that any new matter has been introduced. Favorable consideration of these amendments and allowance of this case are now respectfully requested. The Applicants thank Examiner Aradhana for withdrawing the prior obviousness rejection.

Restriction/Election

The Applicants previously elected with traverse **Group II**, claims 5-7, 10 and 11, directed to an active ingredient containing powder, and the species **(i) anionic antirheumatic** and **(ii) ibuprofen**. The requirement has been made FINAL. The Applicants understand that additional species will be rejoined and examined upon an indication of allowability for a generic claim reading on the elected species. The Applicants respectfully request that the claims of the nonelected group(s) which depend from or otherwise include all the limitations of an allowed elected claim, be rejoined upon an indication of allowability for the elected claim, see MPEP 821.04.

Rejection—35 U.S.C. §103(a)

Claims 5-7, 12-15 and 18-23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kajiyama, et al., U.S. 5,545,492. Kajiyama does not disclose or suggest the invention, because it is directed to a product produced by spray drying (see abstract, col. 10, lines 21 ff. and claims 1 and 13 of Kajiyama) and does not disclose or suggest the process steps now required by independent claim 5.

The process steps required by the invention provide a superior product, less likely to be contaminated or degraded, which differs from that of a spray dried powder, such as that of Kajiyama for the following reasons.

The spray drying method of Kajiyama has a lot of disadvantages that affect product quality and uniformity. If organic solvents are used there are health, residual contamination, and environmental problems caused by the organic solvent. The use of water as a spray drying solvent as in the case Kajiyama, introduces the risk and uncertainty of microbial contamination of the spray dried material, as well as the risk of hydrolysis of the active ingredient or the carrier in the spray dried product by exposure to the water. Spray draying also always causes comparatively high losses of the precious pharmaceutical material in the machinery. Thus, spray drying can result in a qualitative degradation of the product as well as in its quantitative loss during processing.

On the other hand, the inventors have discovered how to make a superior product without introducing the qualitative changes or incurring the other disadvantages of spray drying. These process steps, now recited by claim 5, involve applying a melt process. Since there is no water involved in this melt process, the problems associated with microbial contamination, degradation, and hydrolysis in the presence of water are eliminated. Moreover, the loss of material during processing is reduced compared to a spray drying process.

While some of the ingredients described by Kajiyama are the same as those in the invention, Kajiyama provides no guidance as to which combination of ingredients is useful in a melt process not involving water. For example, col. 8, lines 5-67, of Kajiyama impose "no special restrictions" on the pharmaceutical carrier. Most of these carriers are not suitable for a melt process and only the Eudragit® E type (line 26) polymers have been found to be suitable for combination with higher fatty acids, such as stearic acid (lines 36 – 39).

Moreover, while the invention requires a combination of a higher fatty acid and particular copolymer carriers, Kajiyama provides no suggestion to combine the copolymers listed in col. 8 with higher fatty acids. On the contrary in the list of Kajiyama these substances seem to be listed as substitutes for one another. The Examples in Kajiyama also do not employ the combination required by the invention.

To provide the powder of the invention, the inventors also had to select particular anionic active ingredients from numerous pharmaceutical ingredients described by Kajiyama in combination with the copolymer and higher fatty acid required by the present claims. Kajiyama also fails to suggest this combination of ingredients provided by a melt process. Moreover, Kajiyama uses only **cationic** (famotidine, ambroxol) or **neutral** (acetaminophen) active pharmaceutical ingredients in its examples. On the other hand, comparative examples 6 and 9 of the present application show that (both neutral) caffeine or paracetamol (=identical with acetaminophen) do not work.

The particular combination of ingredients required by claim 5 surprisingly provided a mixture that led to a pharmaceutical form which could be produced advantageously by a melt process and which provides rapid oral release of the pharmaceutical ingredient. This superior bioavailability compared to spray dried products such as those of Kajiyama results from the transfer of the active ingredient to a stadium of a solid solution during the melt process which produces the products of the invention, see U.S. 2006/0051412A1, [0037]). Kajiyama does not suggest the particular selections for ingredients (a), (b) and (c) in claim 5, nor a reasonable expectation of success for the superior release and bioavailability of the active pharmaceutical ingredient provided by the melt process steps used to make the product of the invention. Accordingly, this rejection cannot be sustained.

Rejection—35 U.S.C. §103(a)

Claims 16-17 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kajiyama, et al., U.S. 5,545,492, in view of Smith, et al., U.S. Patent No. 6,194,00. Kajiyama has been discussed above and does not disclose, suggest or provide a reasonable expectation of success for the invention.

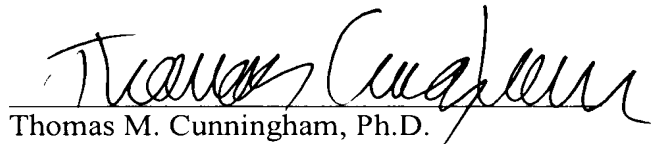
Smith was relied upon as a secondary reference teaching a powder containing an emulsifier having an HLB or at least 14 (*viz.* SDS), but does not disclose or suggest the elements of the invention absent from Kajiyama. Accordingly, this rejection may also be withdrawn.

Conclusion

In view of the amendments and remarks above, the Applicants respectfully request reconsideration of the rejections above and allowance of this application. The Examiner is invited to contact the undersigned at the telephone number below to expedite the resolution of any remaining issues.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



Thomas M. Cunningham, Ph.D.
Registration No. 45,394

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413-2220
(OSMMN 08/07)